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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,574	04/05/2001	Walter Elger	JENA-6	1528

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EXAMINER	
BAHAR, MOJDEH	

ART UNIT	PAPER NUMBER
1617	9

DATE MAILED: 05/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,574	Applicant(s) ELGER ET AL.	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response to the first office action of June 20, 2001, submitted January 22, 2002 (Paper No. 8) is acknowledged.

Applicant's amendments submitted January 22, 2002 in Paper No. 8 are persuasive to remove the objections and rejections under 35 U.S.C. sections 112 and 101 in the previous office action.

Claims 8-17 are herein examined on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 and 24 of copending Application No. 09/755,429. Although the conflicting claims are not identical, they are not patentably distinct from each other because the employment of the estrogen sulfamate in hormone replacement therapy method of claims 8-15 of the instant application is encompassed by the Formula I compounds used in hormone therapy method of claims 23-24 of copending Application No. 09/755,429.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siemann et al. in view of Gale et al. (USPN 5,314694).

Siemann et al. (WO 96/05216) teaches novel estra-1,3,5,(10)-triene amidosulphamates. When R1, R2, R4, R5, R6 and R8 are each H and R7 and R9 are OH, the formula I structure is that of estriol-3-sulphamate within the instant claims, see particularly page 8. Siemann et al. (WO 96/05216) further teaches employing these compounds in compositions and methods for

hormone replacement therapy, see abstract. Siemann et al. (WO 96/05216) also teaches the dosage to be 10 microgram of estradiol, ethinyl-estradiol and estriol per animal per day, see table I.

Siemann et al. (WO 96/05216) does not teach the use of gestagens in its method of hormone replacement therapy; neither does it teach the continued administration of the gestagen.

Gale et al. (USPN 5,314694) teaches the employment of an estrogen along with norprogestrone, in a device useful for continuous transdermal administration, in a method of hormone replacement therapy in women, see claims 11, 13 and 19, col.13-14.

It would have been obvious to one of ordinary skill in the art to employ the estrogen sulfamates in Siemann et al. (WO 96/05216) in combination with gestagens in methods of hormone replacement therapy. It would have also been obvious to administer the gestagen in a continuous manner.

One of ordinary skill in the art would have been motivated to employ a gestagen along with any of the compounds of Siemann et al. (WO 96/05216) in a method hormone replacement therapy because both gestagens and estrogen sulfamates are known to be useful in hormone replacement therapy methods. Combining two agents which are known to be useful in hormone replacement therapy methods individually into a single composition useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven*, 205 USPQ 1069. At least additive therapeutic effects would be reasonably expected. Please note that the method of making a composition by merely mixing or combining ingredients is considered *prima facie* obvious.

Response to Arguments

Applicant's arguments filed January 22, 2002 have been fully considered but they are not persuasive. Applicant argues that none of the cited prior art references teaches the intermittent oral administration of an estrogen sulfamate. Note that the employment of estradiol sulfamate and gestagens for HRT is known in the art. Variations and/or optimizations of the dosage regimen of compounds well known to be useful in HRT together sequentially or simultaneously are considered within the skill of the artisan, absent evidence of the contrary. No such evidence is seen. Note that attorney's arguments as to unexpected results do not take the place of clear and convincing data.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
April 26, 2002